

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD., Plaintiff,)	
v.)	
SAREPTA THERAPEUTICS, INC.,)	C.A. No. 21-1015 (GBW)
Defendant.)	
SAREPTA THERAPEUTICS, INC.,)	
Defendant and Counter-Plaintiff, and)	
UNIVERSITY OF WESTERN)	
AUSTRALIA, Counter-Plaintiff)	
v.)	[REDACTED]
NIPPON SHINYAKU CO., LTD., Plaintiff)	
and Counter-Defendant and)	
NS PHARMA, INC., Counter-Defendant.)	

**NIPPON SHINYAKU CO. AND NS PHARMA, INC.'S
RESPONSE LETTER BRIEF REGARDING MOTION TO EXCLUDE
DR. MATTHEW J.A. WOOD**

Amanda S. Williamson (admitted *pro hac vice*)
Christopher J. Betti (admitted *pro hac vice*)
Krista V. Venegas (admitted *pro hac vice*)
Wan-Shon Lo (admitted *pro hac vice*)
Maria E. Doukas (admitted *pro hac vice*)
Zachary Miller (admitted *pro hac vice*)
Guylaine Haché (admitted *pro hac vice*)
Michael T. Sikora (admitted *pro hac vice*)
Morgan, Lewis & Bockius LLP
110 N. Wacker Drive, Ste 2800
Chicago, IL 60601
Telephone: 312.324.1000
Fax: 312.324.1001
amanda.williamson@morganlewis.com
christopher.betti@morganlewis.com
krista.venegas@morganlewis.com
shon.lo@morganlewis.com
maria.doukas@morganlewis.com
zachary.miller@morganlewis.com
guylaine.hache@morganlewis.com
michael.sikora@morganlewis.com

Amy M. Dudash (DE Bar No. 5741)
Morgan, Lewis & Bockius LLP
1201 N. Market Street, Suite 2201
Wilmington, DE 19801
Telephone: 302.574.3000
Fax: 302.574.3001
amy.dudash@morganlewis.com

Eric Kraeutler (admitted *pro hac vice*)
Alison Patitucci (admitted *pro hac vice*)
Morgan, Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA 19103
Telephone: 215.693.5000
Fax: 215.963.5001
eric.kraeutler@morganlewis.com
alison.patitucci@morganlewis.com

*Attorneys for Plaintiff/Counterclaim Defendant
Nippon Shinyaku Co., Ltd. and Counterclaim
Defendant NS Pharma, Inc.*

Dated: August 9, 2023

Judge Williams:

Pursuant to the Court's July 28, 2023 Oral Order (D.I. 289), Nippon Shinyaku Co., Ltd. and NS Pharma, Inc. (collectively, "NS") hereby submit their letter brief opposing Sarepta Therapeutics, Inc.'s ("Sarepta") and the University of Western Australia's ("UWA") Motion to Disqualify NS's Expert Matthew JA Wood (D.I. 298).

I. FACTUAL BACKGROUND

NS engaged Dr. Wood not because he was Sarepta's previous expert, but because his prior public opinions concerning the state of the art of using antisense oligonucleotides (AOs) for treating Duchenne Muscular Dystrophy (DMD) by exon skipping squarely align with NS's positions in this litigation. Sarepta seeks to disqualify Dr. Wood in order to avoid being confronted with the inconsistent positions it has taken before the USPTO and this Court.

Sarepta paints its relationship with Dr. Wood as one that is long-standing and litigation oriented. Not so. The only potentially relevant [REDACTED]

[REDACTED], and which Dr. Wood consciously chose not to [REDACTED]. Wood Decl. ¶¶ 6-9. Under the [REDACTED], Dr. Wood [REDACTED] related to patent disputes between UWA and third party Academisch Ziekenhuis Leiden ("AZL") titled Interference Nos. 106,007, 106,008, and 106,013 before the USPTO Patent Trial and Appeal Board (collectively, the "Interferences"). *Id.* ¶ 6. The [REDACTED]

[REDACTED] Dr. Wood is not aware of receiving or possessing any confidential or privileged information of Sarepta or UWA [REDACTED] and does not recall the substance of any such information. *Id.* ¶¶ 7, 8.

Dr. Wood also separately [REDACTED] in 2017. *Id.* ¶ 10. Dr. Wood [REDACTED]. *Id.* Although Dr. Wood could not independently recall any information related to exon 53 [REDACTED], Sarepta's [REDACTED]. *Id.*

Dr. Wood has no current agreements with Sarepta or UWA nor has he served as an expert in a case related to the asserted UWA patents or in any dispute with NS. *Id.* ¶ 9, 11. Dr. Wood has not received any confidential or privileged information from Sarepta or UWA concerning this litigation. *Id.* ¶ 12. Dr. Wood is capable of serving as an expert in this matter without divulging or using any confidential or privileged information he may have received from Sarepta—not only because he cannot recall the substance of any such information (*id.* ¶¶ 7-8, 10)—but also because such information will not be implicated by his work in this litigation.

II. LEGAL STANDARDS

Disqualification of an expert is a drastic remedy and is therefore rarely warranted. *Syngenta Seeds, Inc. v. Monsanto Co.*, No. 02-1331-SLR, 2004 WL 2223252, at *1 (D. Del. Sept. 27, 2004); *H. Lundbeck A/S v. Apotex Inc.*, No 18-88-LPS, 2020 WL 1285834, at *1 (D. Del. Mar. 18, 2020). Courts weigh three factors in considering a motion to disqualify an expert: (1) whether the expert had a confidential relationship with the party seeking disqualification, (2) whether "any confidential or privileged information was disclosed to the expert," and (3) "the public interest in allowing or not allowing an expert to testify." *Merck Sharp & Dohme Corp. v. Teva Pharms. USA, Inc.*, No. 14-874-SLR/SRF, 2015 WL 5163035, at *2 (D. Del. Sept. 3, 2015) (quoting *Koch*

Refining Co. v. Jennifer L. Boudreau MV, 85 F.3d 1178, 1181 (5th Cir. 1996)). The party seeking disqualification bears the burden of proof on each factor. *Id.* “Confidential information, in the context of expert disqualification, includes discussion of: litigation strategy . . . the strengths and weaknesses of each side” and other work product information concerning ***the present litigation***. *Syngenta*, 2014 WL 2223252, at *3. “Purely technical information is not confidential information” in this inquiry. *Koch Refining*, 85 F.3d at 1182.

III. ARGUMENT

Sarepta has not and cannot establish that Dr. Wood’s disqualification is warranted here. Sarepta must “provide specific and unambiguous evidence” to establish the relationship between information provided to Dr. Wood and ***this litigation***. *Auto-Kaps, LLC v. Clorox Co.*, No. 15-1737 (BMC), 2016 WL 1122037, at *3 (E.D.N.Y. Mar. 22, 2016) (disqualifying expert because he consulted on the very project that culminated in the design at issue in the litigation, and was exposed to Clorox’s patent strategy). Instead, Sarepta has made “mere conclusory or *ipse dixit* assertions” that are insufficient to meet its burden. *Id.*

Unlike in *Merck*, Dr. Wood’s prior [REDACTED] related to different patents and subject matter than those at issue in this litigation. *Cf. Merck*, 2015 WL 5163035, at * 3 (noting cases involved same patent and active ingredient, and bioequivalent formulations). Specifically, two of the Interferences involved patents that claim AOs for inducing exon 51 skipping—not exon 53 skipping. Exhibit 1; Exhibit 2. The third, No. 106,007, related to the validity of claims to a genus of AOs for inducing exon 53 skipping, but Dr. Wood’s opinions primarily related to the validity of third party AZL’s claims—not the claims at issue in ***this*** litigation. *Compare* Exhibit 3 at 45-46 with Exhibit 4 at cl. 1; Exhibit 5. While Dr. Wood offered opinions on whether a prior art reference by Van Ommen et al., anticipated claims of UWA U.S. Patent No. 8,455,636 patent, that patent, despite sharing a specification and priority claim as the UWA patents at issue in this litigation, is not directly related to and ***claims a different genus*** of AOs. And, regardless of what confidential information may have been shared with Dr. Wood, his ultimate opinions and testimony in the Interferences—which were decided seven years ago—are ***public record***. [REDACTED]

Sarepta’s assertions that

“[REDACTED]” (Evans Decl. ¶ 27, D.I. 299) are conclusory and generalized, and do not identify any specific confidential and privileged information that was shared with Dr. Wood or explain how any such information relates to the present litigation. This is insufficient to meet Sarepta’s burden. *See Syngenta*, 2014 WL 2223252, at *3. [REDACTED]

However, such purely technical information is ***irrelevant*** to the issue of expert disqualification. *Koch Refining*, 85 F.3d at 1181. Regardless, Sarepta fails to establish that any of these materials relate to exon 53, much less the patents at issue in this litigation; Sarepta currently has three FDA-approved AOs that each target different exons and an FDA-approved gene therapy in addition to several treatments in development, and an extensive patent portfolio. Moreover, Dr. Wood does not recall the substance of such discussions, mooted the issue of inadvertent disclosure. Wood

Decl. ¶ 10; *see Hansen v. Umtech Industrieservice Und Spedition, GMBH*, No. 95-516-MMS, 1996 WL 622557, at *7-8 (D. Del. July 3, 1996) (“if the expert himself can’t remember any of the information” there can be “no prospect of future inadvertent disclosure”).

Sarepta’s arguments that [REDACTED] are similarly unavailing. “Unlike attorney-client communications, discussions between parties or counsel and experts do not carry the presumption that confidential information was exchanged.” *Hewlett-Packard Co. v. EMC Corp.*, 330 F. Supp. 2d 1087, 1094 (N.D. Cal. 2004). Moreover, a party seeking to disqualify an expert it retained in a prior litigation must show that the expert was privy to privileged information above and beyond the trial strategy used in that prior case. *H. Lundbeck A/S*, 2020 WL 1285834, at *2 (refusing to disqualify expert who served as a consultant and expert to plaintiff in decade-old litigations involving different patents and different drugs). Sarepta’s generic arguments and evidence (Evans Decl. Exs. 5 and 8, D.I. 299-1 at 110-112 and 115-116) provide no insight as to whether it in fact disclosed [REDACTED] to Dr. Wood, much less that any such disclosure concerned **this litigation**. Thus, Sarepta has failed to meet its burden. *Syngenta*, 2004 WL 2223252 at *3; *H. Lundbeck A/S*, 2020 WL 1285834, at *2; *Novartis AG v. Apotex Inc.*, No. 09-5614 (PGS), 2011 WL 691594, at *4 (D.N.J. Jan. 24, 2011) (denying motion to disqualify where movant “failed to identify any confidential information specific to the subject matter underlying this litigation” and finding general allegations that the expert was received confidential information relating to “legal strategies” insufficient).

The public interest in “guaranteeing that parties have access to expert witnesses who possess specialized knowledge and allowing experts to pursue their professional callings” also weighs in favor of denying Sarepta and UWA’s motion. *Space Sys./Loral v. Martin Marietta Corp.*, No. 95-20122 SW, 1995 WL 686369, at *2 (N.D. Cal. Nov. 15, 1999); *see also Syngenta*, 2004 WL 2223252, at *3 (considering expert’s conscious decision to turn down consulting position with defendant and take position with the plaintiff in the instant litigation to “marshal[] in favor” of allowing expert to testify). Disqualifying Dr. Wood from consulting for NS notwithstanding his decision to end his relationship with Sarepta years ago would unduly and unnecessarily constrain his abilities to pursue his professional calling and interests. Moreover, expert reports are due in less than one month on September 5, 2023. Finding an expert at this stage who has Dr. Wood’s depth of the knowledge related to the state of the art of exon skipping therapies for treatment of DMD is unlikely given the relatively small number of potential experts. Wood Decl. ¶ 2. Therefore, NS would be highly prejudiced by the disqualification of Dr. Wood. *See Space Sys.*, 1995 WL 686369, at *2 (denying motion to disqualify where, *inter alia*, the non-movant would suffer great hardship).

Finally, this is not a case of switching sides in the same litigation that justifies disqualification. *See Koch Refining*, 85 F.3d at 1181. It is undisputed that Sarepta never approached Dr. Wood in connection with **this litigation**. Nor is Dr. Wood a current Sarepta executive or former long-time employee of the patent owner and named inventor of the patent at issue. *Cf. Flight Instrument Corp. v. Sundstrand Data Control Inc.*, 682 F. Supp. 20, 22 (D. Del. 1988) and *Lifewatch Serv. Inc. v. Bramer, Inc.*, No. 09-C-6001, 2010 WL 3909483, at *2-3 (N.D. Ill. Sept. 28, 2010) (cited by Sarepta). Dr. Wood believes he can serve as NS’s expert without violating any obligations to Sarepta. The Court should deny Sarepta and UWA’s motion to disqualify, and allow him to do so.

August 9, 2023

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

/s/Amy M. Dudash

Amy M. Dudash (DE Bar No. 5741)
1201 N. Market Street, Suite 2201
Wilmington, DE 19801
Telephone: 302.574.3000
Fax: 302.574.3001
amy.dudash@morganlewis.com

Eric Kraeutler (admitted *pro hac vice*)
Alison Patitucci (admitted *pro hac vice*)
1701 Market Street
Philadelphia, PA 19103
Telephone: 215.693.5000
Fax: 215.963.5001
eric.kraeutler@morganlewis.com
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*Attorneys for Plaintiff/Counterclaim
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Guylaine Haché (admitted *pro hac vice*)
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Morgan, Lewis & Bockius LLP
110 N. Wacker Drive, Ste 2800
Chicago, IL 60601
Telephone: 312.324.1000
Fax: 312.324.1001
amanda.williamson@morganlewis.com
christopher.betti@morganlewis.com
krista.venegas@morganlewis.com
shon.lo@morganlewis.com
maria.doukas@morganlewis.com
zachary.miller@morganlewis.com
guylaine.hache@morganlewis.com
michael.sikora@morganlewis.com